



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 31 2000

The Honorable Tom Bliley
Chairman, Commerce Committee
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your May 5 letter about the Clinton Administration's efforts to obtain fair prices for the limited number of drugs that Medicare currently covers. We have closely monitored the investigations of drug pricing conducted by the Department of Justice, the HHS Inspector General, and the State Medicaid Fraud Control Units. Let me assure you that I share your concern about the significant discrepancies between the prices that Medicare must pay by law and the significantly lower prices at which physicians may obtain these drugs. I appreciate the opportunity to explain what we have done and the challenges we face in ensuring that Medicare pays fair prices.

History: The Health Care Financing Administration has been actively working to address this issue, both legislatively and through administrative actions, for many years. In 1991, the agency issued regulations to pay for these drugs based on the lower of the estimated acquisition cost or the average wholesale price. To implement this policy, HCFA developed a survey to get the necessary information from physicians. However, given the wide range of drugs used in different amounts at different frequencies by different types of physicians in different geographic areas of the country, we would have had to survey virtually all physicians in order to get a statistically valid estimate of acquisition costs. Because that would have been burdensome and unfeasible, the Administration therefore determined that it would rely instead on the average wholesale price.

Because the estimated acquisition cost approach had proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration's proposal. Instead, the Balanced Budget Act reduced Medicare payment for covered drugs from 100 percent to 95 percent of average wholesale price. This recaptures only a fraction of the excessive Medicare payment amounts because, until recently, available average wholesale price data did not correlate to actual wholesale prices for certain Medicare-covered drugs.

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Indeed, the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community. Therefore, in 1998, the President again proposed paying physicians their actual acquisition cost to "ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients." However, no Congressional action was taken.

Because Congress failed to act on the Administration's 1997 and 1998 proposals, in 1999 and again this year, the President proposed a different legislative approach to achieve a similar result -- paying 83 percent of the average wholesale price instead of the 95 percent allowed by the Balanced Budget Act. We estimate that this would substantially reduce the pricing discrepancy, as well as any administrative burden associated with surveying vast numbers of physicians to estimate acquisition costs. The HCFA actuaries project that this legislative proposal would save Medicare \$2.9 billion over 10 years.

Current Activity: We are now moving administratively to take advantage of the newly available, more accurate data on average wholesale prices developed for Medicaid as a result of Department of Justice investigations. These data are from catalogs of drug wholesalers, which the Department of Justice says account for a significant portion of the wholesale market. The Department of Justice and the State Medicaid Fraud Control Units have compiled data for about 400 national drug codes, representing about 50 different chemical compounds. The Department of Justice provided this information to First Data Bank, a company specializing in the compilation of drug pricing data (formerly known as the "Blue Book") that is used to determine prices paid by State Medicaid programs. These drugs represent about one-third of Medicare spending for drugs.

To obtain the benefits of this new information for Medicare right away, we will provide to the insurance companies that, by law, Medicare must contract with to pay Part B claims (known as "carriers") the average of the wholesale catalog prices, just as has been calculated by First Data Bank. In June, we will send this information to Medicare carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances, which will become effective on October 1, 2000. According to the HHS General Counsel, this is the most immediate action we can take without undergoing the formal rule-making process.

We also are consulting with the Department of Justice and HHS Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare rates. To monitor carrier activities, we are requiring carriers to send to HCFA by September 15, 2000, a written explanation of the data sources used for determining payment allowances for these drugs. And we are attempting to meet with the company that publishes the "Red Book," which is the source of average wholesale price data that most carriers have used to date, to discuss recent developments and the need for accurate data. Furthermore, we are considering whether to change our current legislative proposal from paying 83 percent of average wholesale prices to instead propose paying physicians their actual acquisition costs.

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Based on our recent discussions with the Department of Justice and HHS Inspector General, we believe that the Administration's original approach -- to base Medicare's payment for drugs on the physician's actual acquisition costs, perhaps adjusted for a reasonable handling fee -- is probably the most effective means to ensure that Medicare is paying fairly. As part of this effort, we plan to work with physician groups to review physicians' ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs themselves to the prices that physicians pay.

Other Efforts: In addition to the proposed legislation and administrative activity discussed above, we are taking several other steps to try to address Medicare drug pricing inequities.

- We are developing an electronic file of prices for Medicare covered drugs, as recommended by the HHS Inspector General in her December 1997 report. I understand your concern about the speed with which our efforts have proceeded, but I want to assure you that HCFA has moved as quickly as was administratively feasible to put this system in place. A contractor has been working on numerous technical issues, including the components necessary for appropriate drug pricing (e.g., route of administration, drug strength concentrations, available package size and most commonly used dosage ranges). We are hopeful that a report on this first phase of the project will be available by this summer. A report on a second phase of work on issues relating to mapping between codes Medicare currently uses (the HCFA Common Procedure Coding System) and national drug codes, compatibility with the Health Insurance Portability and Accountability Act administrative simplification standards that are being developed, generic and brand name mapping, new drug entries, drug deletions, and updates, is expected by the end of the year. We believe this work will help us ensure that all carriers across the country have access to the most accurate average wholesale price data and will reimburse a uniform allowed amount for each drug code.
- We are using market forces and competition to set fairer prices for one drug -- albuterol sulfate -- as part of a competitive bidding demonstration for durable medical equipment supplies in Texas. A similar demonstration in Florida, while not including drugs, is saving an average of 17 percent for beneficiaries and Medicare through the bidding process. We hope to be able to use the results from these demonstrations more generally in the Medicare program.
- Finally, we are awaiting a final General Accounting Office report on use of the "inherent reasonableness" authority contained in the Balanced Budget Act of 1997. In September 1998, we proposed reducing excessive charges on several items, including albuterol sulfate. Our contractors who process durable medical equipment claims surveyed retailers in 16 states and found that Medicare was paying substantially more than other payers.

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Congress, however, in the Balanced Budget Refinement Act of 1999, mandated that we not take action to finalize the proposed rule until a GAO study of our use of the inherent reasonableness authority is published. We just received the draft final report from the GAO and look forward to its final report so we can move forward to reduce these payments to reasonable levels.

We have also taken actions to help State Medicaid programs obtain fair prices for drugs.

- We have proposed sharing average manufacturer price data with States so they can accurately set Medicaid reimbursement rates. Current law only requires drug manufacturers to report average manufacturer price data to HHS.
- We have proposed applying the consumer price index-urban (CPI-U) adjustment to generic drugs. Brand name drug manufacturers must pay an additional dollar-for-dollar rebate to Medicaid if they increase prices in excess of CPI-U. But it is now clear that generic drug prices also sometimes increase faster than inflation.
- We plan to work with all State Medicaid programs regarding First Data Bank's announcement that it will revise the way it collects and reports average wholesale price data to them, based on information in wholesaler catalogs. This should create immediate benefit for all State Medicaid programs.

As you know, the President has proposed a voluntary, comprehensive Medicare outpatient drug benefit available to all Medicare beneficiaries. A critical element of this proposal is the use of private pharmacy benefit managers who will negotiate prices with pharmaceutical companies, as they do now for most private insurance plans. This will help keep the benefit affordable without any statutory price setting, and avoid the types of concerns addressed in this letter.

Again, I thank you for your inquiry into this important matter. We would be very interested in receiving the data the Commerce Committee has compiled on Medicare drug pricing to assist our efforts. We hope Congress will enact the President's proposal for improving Medicare drug payments, and I look forward to working further with you and your Committee as we proceed.

Sincerely,



Donna E. Shalala

CRL WHITE HOUSE RELEASE OF 50 DRUGS WHOSE PRICES WILL BE CUT OCT 1
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List of Medicare drugs with new data on wholesale prices

ACETYLCYSTEINE	HEPARIN LOCK FLUSH
ACYCLOVIR SODIUM	HYDROCORTISONE SODIUM SUCCINATE
ALBUTEROL SULFATE	IMMUNE GLOBULIN
AMIKACIN SULFATE	INFED
AMINO ACIDS	KYTRIL
AMPHOTERCIN B	LEUCOVORIN CALCIUM
ANTI-INHIBITOR COAGULANT COMPLEX	LORAZEPAM
ANZEMET	LUPRON
BLEOMYCIN SULFATE	METAPROTERENOL SULFATE
CALCITROL	METHOTREXATE SODIUM
CIMETIDINE HYDROCHLORIDE	METHYLPREDNISOLONE SODIUM SUCCINATE
CISPLATIN	MITOMYCIN
CLINDAMYCIN PHOSPHATE	PENTAMIDINE ISETRIONATE
CROMOLYN SODIUM	SODIUM CHLORIDE
CYCLOPHOSPHAMIDE	TESTOSTERONE CYPIONATE
CYTARABINE	TESTOSTERONE ENANTHATE
DEXAMETHASONE ACETATE	TOBRAMYCIN SULFATE
DEXAMETHASONE SODIUM PHOSPHATE	VANCOMYCIN HYDROCHLORIDE

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